Executive Summary

Chapter 481 of the 2002 Acts of Assembly amended the *Code of Virginia* to create a prescription monitoring program as a pilot program limited to State Health Planning Region III in Southwest Virginia. The Department of Health Professions was awarded a federal grant through the Harold Rogers Prescription Drug Monitoring Program to implement and support initial operations of the program in April 2003. An additional grant was awarded in 2004 for the purposes of sponsoring a conference on prescription drug abuse and prescription monitoring programs and to conduct a survey of practitioners regarding the prescribing of controlled substances and their impressions of the program.

In June 2003, the Director formed an advisory committee to assist in the implementation and evaluation of the program. The committee advises the Department on the extent to which the legislation has been successfully implemented, any changes that should be made in policies and practices of the program, what aspects of the program should be evaluated and any other issues related to the illegal diversion of controlled substances or access to appropriate drug therapy. The committee has met quarterly beginning in September 2003 and has been instrumental in developing an evaluation workplan for the program, determining policy issues and making recommendations resulting from the review of these issues.

The program began operations in September 2003 with prescriptions dispensed for Schedule II controlled substances being submitted by approximately 300 pharmacies and other dispensers twice a month. Currently, the database contains over 460,000 prescription records and over 1000 requests for information from the program have been processed.

Review of data collected thus far appears to show that the implementation of the program has not had a "chilling" effect on the legitimate prescribing of Schedule II controlled substances. The amount of oxycodone and hydrocodone being distributed in wholesale distribution channels continued to increase throughout Virginia at a rate of 9% and 8% respectively in 2002 and 2003. Information maintained by the Department of Medical Assistance Services (DMAS) shows that after a substantial drop in claims for oxycodone containing prescriptions in the 1st and 2nd quarters of 2002, the number of

claims submitted in the 1st quarter of 2004 for these products are 21% higher than they were in the 1st quarter of 2001. A survey was conducted in mid-2004 and compiled by the Survey and Evaluation Research Laboratory, Virginia Commonwealth University and sponsored by the American Cancer Society (ACS) and the South Atlantic chapter of the ACS, in collaboration with the Virginia Cancer Pain Initiative. Physicians were asked if in the past three years, they have been prescribing fewer Schedule II controlled substances. 36% of respondents reported prescribing fewer Schedule II drugs; of these, 48% cited intense media coverage and 41% cited increased law enforcement activity as the reason for prescribing fewer Schedule II prescriptions. 31% of these practitioners reported that prescribing fewer Schedule II drugs had a negative impact of helping patients manage their pain while 61% reported no impact.

A concern of having a pilot program in only the southwest portion of the Commonwealth was that the illegal activity of prescription drug diversion would move to outside the program area. Data from the Drug Diversion Unit of the State Police appears to confirm that concern. Data comparing 2003 to 2004 shows complaints received by the unit increased by 26% statewide while decreasing in the program area by 47%. Arrests increased by 35% statewide versus 31% in the program area. It also appears that using the program may save substantial man-hours in performing investigations with data from the program area showing a 53% decrease in man-hours spent doing pharmacy profiles between 2003 and 2004.

Accidental deaths due to prescription drug abuse or misuse continues to be a significant public health concern in Virginia, especially the southwest region of the Commonwealth. Since 2000, there has been a 100% increase in drug deaths in the Western District of the Office of the Chief Medical Examiner. Statewide in 2003, there were 223 drug deaths reported in the Western District, 101 in the Tidewater District, 106 in the Central District and 108 in the Northern District. In the Western District, 44.6% of the cases identified methadone as the cause of death followed by hydrocodone, oxycodone, fentanyl and propoxyphene.

The issue of prescription drug abuse is not limited to Virginia. The President's 2004 National Drug Control Strategy highlighted the problem, reporting that the non-medical use of addictive prescription drugs has been increasing throughout the United

States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past-month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. To combat this problem several approaches are being developed, including education and training on appropriate pain management and opioid treatment procedures for practitioners, increasing the number of state prescription monitoring programs, and using technology to identify, investigate, and prosecute "pill mills" including internet pharmacies that provide controlled substances illegally.

In May 2004, Department staff developed a list of policy issues that became evident as a result of the evaluation workplan. These policy issues were reviewed at the June and September 2004 meetings of the Advisory Committee and recommendations were made based on those issues.

Limitations in Coverage: The program in its current form has two limitations in coverage which make it less than effective. First, the program is limited geographically to pharmacies in Southwest Virginia (Health Planning Region III). This means that pharmacies outside of this area do not report to the program. This gives an incomplete picture of what a patient may be receiving or a prescriber may be writing. For example, several prescribers querying the system have reported that although the system showed no prescriptions filled for a particular patient, they knew that they had written prescriptions for that patient. The patient is most likely having the prescriptions filled by a pharmacy outside the geographical area, or by a mail order pharmacy which is not covered by the current program. Individuals who engage in "doctor shopping" for the purpose of obtaining controlled substances for illicit use are very savvy about drug laws, frequently travel many miles to visit numerous physicians and pharmacies, and will avoid having their prescriptions filled in pharmacies within the program area to prevent detection.

Second, the program is limited in scope, only covering prescriptions written for drugs classified in Schedule II. While by definition Schedule II drugs have the greatest potential for abuse, it has been reported by those who deal with illicit pharmaceutical

diversion that most abuse occurs in other schedules. Data shows that hydrocodone products such as Vicodin or Lortab, Schedule III drugs, are more often abused in Virginia than Schedule II drugs. Benzodiazepine products, such as Valium or Xanax, Schedule IV drugs, are also frequently abused, often in combination with other products. Because pharmacies only report Schedule II prescriptions, prescriptions filled for these other scheduled drugs are not captured and the program is defeated. Again, street-smart doctor shoppers and physicians running "pill mills" are aware of the program and will avoid prescriptions for Schedule II drugs to prevent detection.

Access to the Data: The Virginia PMP appears to be the most restrictive prescription monitoring program in the nation in terms of limiting access to the prescriber and dispenser. In other states up to 90% of all queries come from prescribers who query monitoring systems for the purpose of "establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient." This allows a prescriber to avoid being duped into providing drugs to individuals for illegitimate purposes and to detect a patient who has a serious substance abuse problem. It also allows a prescriber to refer a patient for treatment, change prescriptions, or otherwise provide better medical care. However, Virginia law requiring a patient's written, informed consent adds to the significant burden that currently exists in a busy physician's office and makes this important feature of drug monitoring less useful. Also, under Virginia law, a dispenser (pharmacist) is not authorized to query the system at all. This is not the case in most other states' programs. The ability of pharmacists to query the system when a questionable prescription is presented can prove to be a great aid in meeting their obligation to dispense only for an appropriate medical purpose.

Wording in the law restricts access to the personnel of the Department of Health Professions to cases relating to indiscriminate prescribing and dispensing. Investigators from the State Police, in addition to requesting information related to prescribing and dispensing, may also request information related to a patient. DHP staff has authority in law to obtain prescription information through traditional means on licensees of DHP who are under investigation for personal drug diversion or misuse as recipients, and

should also be able to access the program in these same cases to streamline case investigation time and reduce man-hours.

Analysis of the data maintained by the program: Current law does not permit any entity, including DHP, to examine the prescription information that is in the system. In the first year of data collection the Department compiled over 400,000 records of Schedule II drugs in the covered area. It is likely that careful analysis of this data can contribute to identification of poor practice and illegal activity. Needless to say, such analysis and use of the information contained in this system must be carefully crafted in such a way as to not inhibit the appropriate delivery of care nor result in unfair and unfounded accusation of violations of law or regulation.

Nevada's administration of its more developed prescription monitoring effort has resulted in a significant reduction in "doctor shopping" by analyzing the data for the purpose of providing unsolicited reports of possible "doctor shopping" to physicians about their patients. Nevada has developed strict criteria for identifying possible criminal drug diversion based on the number of physicians that one patient may see and numbers of controlled substances obtained. The criteria have been designed to screen out patients seeing multiple physicians for legitimate medical purposes. The "medical model" of providing information to those prescribers may be the greatest benefit in achieving a reduction in prescription drug abuse. Virginia law does not currently authorize the analysis of the data for this purpose.

Funding: At the current time the program is operating on funds generated from federal sources. It also appears that unmatched grants maybe available for the next several years to continue operation of this program. However, there is no guarantee that this situation will continue indefinitely. If the state finds that this program is effective in helping to address the serious and growing problem of prescription drug abuse in the Commonwealth, a commitment to fund this activity should be addressed.

Practitioner education: A question has been raised concerning what a practitioner can do and what his responsibility is for a patient who appears to be "doctor-shopping" or is abusing prescription controlled substances. While a common occurrence is the discharge of the patient from the practice or the refusal to write a prescription, the practitioner and the patient may benefit from the practitioner having access to guidance

on referring for treatment, when and how to report suspicions of criminal activity to law enforcement, and how to properly manage a patient receiving treatment with controlled substances.

The recommendations of the Advisory Committee as endorsed by the Department of Health Professions and the Virginia State Police are as follows:

1. Continue the program indefinitely;
2. Expand the program to include Schedule II through IV controlled substances;
3. Expand the program to the entire Commonwealth;
4. Allow pharmacists to access the program;
5. Allow a prescriber licensed in another state to request information from the PMP;
6. Allow access to the PMP for DHP investigative personnel and designated HPIP personnel on a specific licensee, registrant, or certificate holder where there is an open investigation;
7. Allow Medical Examiners access to the PMP for the purpose of performing their duties in accordance with §32.1-287;
8. Allow access to The Department of Medical Assistance Services for the purpose of investigating fraud when there is an open investigation on a recipient;
9. Allow access to the Drug Enforcement Agency when there is an open investigation on a prescriber or dispenser;
10. Allow access to the program for research purposes to public and private entities where all personal identifying information is removed;
11. Allow access to the program for health/education purposes, providing information to prescribers and dispensers on their patients who may be abusing, misusing, or fraudulently obtaining controlled substances ; and
12. Require non-resident pharmacies to report to the program.

A draft of the proposed legislation which embodies these recommendations is found in Appendix A.